

REMARKS

Claims 19-53 and 55-59 have been canceled as drawn to a non-elected invention. Additionally, claims 7, 8 and 11 have been canceled. New claim 60 has been added. Upon entry of this Amendment, claims 1-6, 9, 10, 12-18, 54 and 60 will be pending.

Claims 1, 9 and 10 have been amended. Claims 1 and 10 have been amended to further recite that the embryonic-like stem cells are OCT-4⁺ and ABC-p⁺, incorporating limitations originally found in claim 11. Support for the amendment to claim 9 may be found at page 17, lines 7-8. Claims 9, 17 and 18 have been amended to delete dependency on canceled claim 7 and to recite dependency on claims 1, 10 and 10, respectively. No new matter has been introduced by this amendment. Claim 54 has been amended to recite a placenta engrafted with a non-fetal, non-maternal cell. Support for amended claim 54 may be found at page 26, lines 28-30. Support for new claim 60 may be found at page 18, lines 10-12. Thus, new claim 60, and the amendment of claims 1 and 10, add no new matter.

Claim Objections

The Examiner has objected to claim 11 for reciting "OCT-4" and "ABC-p," stating that these terms should be spelled out the first time they appear in the claims. Claim 11 has been canceled, mooting the Examiner's objections with respect to this claim. However, with regard to claims 1 and 10 as amended, with respect, Applicants point out that persons of skill in the art use the terms "OCT-4" and "ABC-p" when referring to these two particular markers. Hence, no spelling out of the terms is needed for clarity.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claim 11 under 35 U.S.C. § 112, second paragraph as indefinite in its recitation of "OCT-4". Applicants have canceled claim 11, mooting the Examiner's rejection of claim 11 on this basis.

The Examiner has also rejected claim 11 35 U.S.C. § 112, second paragraph as indefinite in its recitation of "ABC-p⁺" because the term "ABC" is apparently also used by those in the art to stand for "antibodies bound/cell" and "antibody binding capacity" as well as "placenta ABC protein. Applicants have canceled claim 11, mooting the Examiner's rejection of claim 11 on this basis; however, claims 1 and 10 as amended contain this limitation.

With respect to claims 1 and 10 as amended, this term is sufficiently definite. With respect, in the context of these claims, no person of skill in the art would read "ABC-p" to

mean “antibodies bound/cell” and “antibody binding capacity”. First, to do so would be to read the claims as reciting “embryonic-like stem cells that are . . . antigen binding capacity” or “embryonic-like stem cells that are . . . antibodies bound/cell.” Rather, a person of skill in the art would interpret claims 1 and 10 as reciting two markers, one of which is “ABC-p.” Second, “ABC-p” refers to a protein (hence “-p”), something which “ABC” in the other two contexts mentioned by the Examiner does not. Moreover, the specification teaches that “ABC-p” is a marker, but does not teach that ABC may be interpreted as “antibodies bound/cell” or “antibody binding capacity.” Thus, the use of the term “ABC-p” in claims 1 and 10 is sufficiently definite.

The Rejections Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-10 and 12-18 under 35 U.S.C. § 102(b) as anticipated by Sanders, U.S. Patent No. 3,862,002 (“Sanders”). The Examiner contends that Sanders teaches a human placenta that is recovered after birth, exsanguinated, incubated in sterile medium containing anticoagulant or antibiotic, preferably within 6 hours of delivery; teaches that the perfusion medium contains growth factors; teaches that the perfusion period could last for days, as there is a 3-5 day lag for re-establishing metabolic activity; and, because “it is known that the placenta contains hematopoietic stem cells under normal physiological condition[s] as evidenced by Kurtzberg et al.,” (Office Action, pages 3-4) teaches conditions under which embryonic-like stem cells are produced.

Applicants have canceled claims 7 and 8, mooted the Examiner’s rejection of these claims.

Applicants have amended claim 9 to depend from claim 1, and claims 17 and 18 to depend from claim 10. Thus, as amended, claims 1-6, 9, 12, 13, 15, and 17 depend from claim 1, and claims 14, 16 and 18 depend from claim 10. Applicants have amended claims 1 and 10 to recite that the embryonic stem cells are OCT-4⁺ and ABC-p⁺. Sanders does not teach that the placenta, or placental parts, disclosed therein comprise or produce embryonic-like stem cells that are OCT-4⁺ and ABC-p⁺. Sanders therefore does not anticipate any of claims 1-6, 9, 10, or 12-18 as amended.

The Examiner relies on Kurtzberg *et al.*, *New Engl. J. Med.* 335:157-166 (1996) (“Kurtzberg”) as teaching that hematopoietic stem cells may be obtained from the placenta. However, Kurtzberg teaches obtaining hematopoietic stem cells from placental *blood*, not from the placenta itself. Kurtzberg does not teach that the stem cells are derived from the

placenta. The instant specification, in contrast, teaches that the embryonic-like stem cells are derived from the placenta itself. Thus, Kurtzberg does not teach the stem cells recited in claims 1 or 10, and therefore does not support anticipation of the claims by Sanders.

The Examiner also rejects claims 1-5, 7-10, 12-14, 16-18 under 35 U.S.C. § 102(b) as anticipated by Muhlemann *et al.*, *Placenta* 16:367-373 (1995) (“Muhlemann”). The Examiner contends that Muhlemann teaches a human placenta that is recovered after birth, exsanguinated, incubated in a sterile medium containing anticoagulant and antibiotics, for a total of 11.5 hours, where the perfusion solution contained growth factors (Office Action, page 5). The Examiner also contends that the placenta of Muhlemann “was maintained under normal physiological condition[s], thus meet[ing the] claim limitation for production of embryonic-like stem cells (*id.*). ”

Applicants have canceled claims 7 and 8, thus mooted the Examiner’s rejection of these claims.

Applicants have amended claim 1 to recite that the placenta produces embryonic-like stem cells that are OCT-4⁺ and ABC-p⁺, and have amended claim 10 to recite that the recited embryonic-like stem cells are OCT-4⁺ and ABC-p⁺. Muhlemann does not teach a placenta that produces embryonic-like stem cells that are OCT-4⁺ and ABC-p⁺. In fact, Muhlemann does not teach a perfused placenta as contemplated by the present invention, as the placenta of Muhlemann is heavily infected with cytomegalovirus during the perfusion. As such, it would not be useful for the production of embryonic-like stem cells as described in the present specification. Muhlemann, therefore, does not anticipate any of claims 1-5, 9, 10, 12-14 or 16-18 as amended.

Finally, the Examiner has rejected claim 54 under 35 U.S.C. § 102(b) as anticipated by Ordi *et al.*, *Am. J. Surg. Pathol.* 8:1006-1011 (1998) (“Ordi”). The Examiner contends that the claim is directed to a placenta that contains a cell that is neither fetal nor maternal in origin, and that Ordi teaches a placenta containing malaria parasite cells. Applicants have amended claim 54 to recite a placenta *engrafted with* non-fetal, non-maternal cell, to emphasize that the cell is placed into the placenta deliberately, as opposed to an infective process. Ordi does not teach a placenta engrafted with a non-fetal, non-maternal cell. Thus, Ordi does not anticipate claim 54 as amended.

Based on the above amendments and arguments, Applicants respectfully state that the cited references do not anticipate any of the claims as amended. Applicants therefore request that the Examiner withdraw the rejections of the claims under 35 U.S.C. § 102(b).

The Double Patenting Rejection

The Examiner has provisionally rejected claims 1 and 6-10 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending application no. 10/074,976. Applicants have canceled claims 7 and 8, mooted the Examiner's provisional rejection of these claims. With respect to claims 1, 6, 9 and 10, Applicants respectfully request that the Examiner hold this provisional rejection in abeyance until such time as relevant claims in either the present application or in application no. 10/076,976 are allowed.

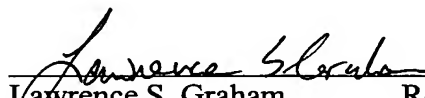
Conclusion

For the reasons provided above, the claims as amended should now be in condition for allowance, and early notice of the same is earnestly solicited. Applicants believe that no fee is due for this Amendment. However, if a fee should be deemed due, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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